



Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

MEMORANDUM

TO: Local Health Officers

FROM: Judy Monroe, MD
State Health Commissioner

DATE: May 1, 2009

RE: Federal & State Legal Requirements for Dispensing Antivirals

The purpose of this memorandum and the accompanying documents is to advise Local Health Officers and local health departments as to the Federal and State legal requirements for dispensing antivirals from the Strategic National Stockpile, as well as State and local government stockpiles.

AT THIS TIME, THE ANTIVIRALS RECEIVED FROM THE STATE SHOULD NOT BE DISPENSED, BUT SHOULD REMAIN SECURE AND STORED AT ROOM TEMPERATURE (BETWEEN 59 AND 86 DEGREES FAHRENHEIT). THESE ANTIVIRALS HAVE BEEN DISTRIBUTED TO LOCAL HEALTH DEPARTMENTS FOR PRE-POSITIONING PURPOSES ONLY AND SHALL REMAIN SECURELY STORED UNTIL THE COMMERCIAL SUPPLY IS DEPLETED AND YOU HAVE RECEIVED FURTHER ADVISEMENT FROM THE INDIANA STATE DEPARTMENT OF HEALTH.

The following information and accompanying documents will assist you in planning for the future distribution and dispensing of the stockpiled medications:

I. Emergency Use Authorizations (EUA)

As you know, a public health emergency has been declared by the U.S. Department of Health & Human Services due to the outbreak of H1N1 influenza infections identified in the United States and abroad.

Tamiflu and Relenza are both FDA-approved antiviral drugs that fight against this novel virus. While Tamiflu and Relenza have been previously approved by the FDA, certain aspects of the distribution and use of these products are not covered by their approved applications. [For example, Tamiflu is approved for the treatment and prevention of influenza in patients 1 year and older. The EUA allows for Tamiflu to be used to treat and prevent influenza in children under 1 year. Also, both Tamiflu and Relenza have been authorized for use at later time points (i.e. – with patients who are symptomatic for more than 2 days).] An Emergency Use Authorization, issued by the FDA, allows these drugs to be legally distributed for the unapproved uses for which they are being authorized. Note that only the FDA-approved facts sheets for each medication are to be

distributed with the medication. **Please see the individual EUA's for both Tamiflu and Relenza for complete information as to the scope and conditions of the authorization.** Be advised that though state and local health departments may provide additional information relating to the emergency use of authorized Tamiflu and Relenza that additional information must be consistent with, and may NOT exceed, the terms of the letters of authorization.

If states and local jurisdictions do not distribute or dispense the antivirals in accordance with the scope and conditions of the EUA, liability protections afforded by the Public Readiness and Emergency Preparedness (PREP) Act may be affected.

Additional information is available online at: <http://www.cdc.gov/h1n1flu/eua/>.

II. Distribution and Dispensing Pursuant to Indiana Law

Please see accompanying memorandum from the Indiana Board of Pharmacy and the Indiana Professional Licensing Agency. This memorandum serves to instruct local health departments as to the methods of proper dispensing available under Indiana law for any legend drug, including antiviral medications. Note that a prescription or drug order is required for the dispensing of antiviral medications. Four examples of legal dispensing are contained in the memorandum and are likely to account for any dispensing scenario at the local level. If circumstances later require a dispensing method not currently within the statutory framework, the Indiana Board of Pharmacy has the authority to suspend the provisions of a statute or rule that would prevent, hinder, or delay the appropriate delivery of pharmaceutical care when a disaster is declared by the Governor pursuant to Ind. Code §10-14-3-12 or by the President of the United States.

If you have further questions about these requirements, please contact Jennifer Bruner by e-mail (jbruner@isdh.IN.gov) or by phone (317.234.2818).

Accompanying Documents:

- Emergency Use Authorization Letter – Tamiflu
- Fact Sheet for Health Care Providers – Tamiflu
- Fact Sheet for Patients – Tamiflu
- Package Insert – Tamiflu

- Emergency Use Authorization Letter – Relenza
- Fact Sheet for Health Care Providers – Relenza
- Fact Sheet for Patients – Relenza
- Package Insert – Relenza

- Memorandum from IPLA and Indiana Board of Pharmacy

